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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,607	07/29/2003	Paula M. McCready	IL-11032	4971

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John H. Lee
Assistant Laboratory Counsel
Lawrence Livermore National Laboratory
P.O. Box 808, L-703
Livermore, CA 94551

EXAMINER	
SALMON, KATHERINE D	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,607	MCCREADY ET AL.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-17* is/are pending in the application.

4a) Of the above claim(s) *4-7 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 10-17* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/25/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1, Claims 8 and 10-17 and SEQ IDs 1-8 in the reply filed on 9/05/2006 is acknowledged.

2. Claims 1-3 have been canceled. Claims 4-7 are withdrawn as being drawn to a nonelected invention. Claim 9 is withdrawn as being drawn to nonelected sequences.

3. An action on the merits for Claims 8 and 10-17 is set forth below.

Abstract

4. The abstract of the disclosure is objected to because the abstract begins with "Described herein". Correction is required. See MPEP § 608.01(b).

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. For example, p. 6 paragraph 11 has a hyperlink. Applicant should go through the specification to remove any other hyperlinks, which may be in the specification.

Claims 11, 14 and 16-17 contain length limitations for the set of oligonucleotides. This length limitation is not provided in the specification. Therefore the specification does not provide any support for the length limitations in Claims 11, 14, and 16-17.

Claim Objections

6. Claim 10 is objected to because of the following informalities: Claim 10 needs to be amended to include the limitations of Claim 9 because Claim 9 is withdrawn. Please amend Claim 10 to include the limitations of Claim 9 without adding withdrawn subject matter (the SEQ IDs). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 8, 10-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 10-17 are indefinite over the recitation of "full length complement" in Claim 8. It is unclear if the "full-length complement" is the complement of the entire SEQ ID No. 4 or 8. It is unclear the limitation of full-length is the complete complement of SEQ ID No. 4 or 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession Number AE008917 (December 28, 2001) in view of DelVecchio et al. (PNAS January 8, 2002 Vol. 99 p. 443).

Genbank Accession Number AE008917 teaches the complete sequence of the genomic DNA isolated by DelVecchio et al. Nucleotides 1347-1164 are a 100% match to SEQ ID No. 4. Nucleotides 1710-1515 are a 100% match to SEQ ID Number 8.

Genbank Accession Number AE008917, however, does not teach a composition comprising a first and second isolated polynucleotide consisting of SEQ ID No. 4 or a full-length complement and SEQ ID No. 8 or a full length complement.

With regard to Claim 8 and 10, DelVecchio et al. teaches B. melitensis strain 16M high molecular weight genomic DNA was isolated was sheared, size fractionated and used to construct libraries (p. 443 2nd column 1st full paragraph). Therefore DelVecchio et al. teaches a composition (sheared DNA in a library) in which various fragments of the B. melitensis sequence is contained. DelVecchio et al. teaches the sequences from the library were combined to assemble a genome, which was deposited as GenBank Accession Numbers AE008917 and AE008918 (p. 443 2nd column 1st full paragraph and foot note).

Therefore it would have been prime facie obvious to one of ordinary skill in the art at the time the invention was made that the high molecular weight genomic DNA which was sequenced in DelVecchio et al. is the nucleotides of GenBank Accession Number AE008917. It would have been obvious to the ordinary artisan that the nucleotides presented in GenBank Accession Number AE008917 are the nucleotides which were sequenced by shear fractionation by DelVecchio et al. because DelVecchio et al. teaches the sequences were deposited as GenBank Accession Numbers AE008917 and AE008918 (p. 443 2nd column 1st full paragraph and foot note).

10. Claims 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession Number AE008917 (December 28, 2001) in view of DelVecchio et

al. (PNAS January 8, 2002 Vol. 99 p. 443) and in further view of Hogan et al. (US Patent 5541308 July 30, 1996).

Genbank Accession Number AE008917 teaches the complete sequence of the genomic DNA isolated by DelVecchio et al. Nucleotides 1347-1164 are a 100% match to SEQ ID No. 4. Nucleotides 1710-1515 are a 100% match to SEQ ID Number 8. With regard to Claims 13 and 15, GenBank Accession Number AE008917 teaches a sequence which encompasses the exact sequences of SEQ ID No. 1-3 and 5-7. Nucleotides 1347-1322 are identical to SEQ ID No. 1. Nucleotides 1164-1190 are identical to SEQ ID No. 2. Nucleotides 1248-1223 are identical to SEQ ID No. 3. Nucleotides 1710-1686 are identical to SEQ ID No. 5. Nucleotides 1515-1540 are identical to SEQ ID No. 6. Nucleotides 1605-1579 are identical to SEQ ID No. 7.

Genbank Accession Number AE008917, however, does not teach a composition comprising a first and second isolated polynucleotide consisting of SEQ ID No. 4 or a full-length complement and SEQ ID No. 8 or a full length complement. Genbank Accession Number AE008917 also does not teach oligonucleotide fragments of SEQ ID 4 and 8.

DelVecchio et al. teaches B. melitensis strain 16M high molecular weight genomic DNA was isolated was sheared, size fractionated and used to construct libraries (p. 443 2nd column 1st full paragraph). Therefore DelVecchio et al. teaches a composition (sheared DNA in a library) in which various fragments of the B. melitensis sequence is contained. DelVecchio et al. teaches the sequences from the library were

combined to assemble a genome, which was deposited as GenBank Accession Numbers AE008917 and AE008918 (p. 443 2nd column 1st full paragraph and foot note).

Hogan et al. teaches the use of specific primers and probes to amplify the 16S region of bacteria. Hogan et al. provides guidance for the selection of probes.

> "Once the variable regions are identified, the sequences are aligned to reveal areas of maximum homology or 'match'. At this point, the sequences are examined to identify potential probe regions. Two important objectives in designing a probe are to maximize homology to the target sequence(s) (greater than 90% homology is recommended) and to minimize homology to non-target sequence(s) (less than 90% homology to non-targets is recommended). We have identified the following useful guidelines for designing probes with the desired characteristics.
> Fist, probes should be positioned so as to minimize the stability of the probe: nontarget nucleic acid hybrid. This may be accomplished by minimizing the length of perfect complementarily to non-target organisms, avoiding G and C rich regions of homology to non-target sequences, and by positioning the probe to span as many destabilizing mismatches as possible (for example, dG:rU base pairs are less destabilizing than some others). Second, the stability of the probe: target nucleic acid hybrid should be maximized. This may be accomplished by avoiding long A and T rich sequences, by terminating the hybrids with G: C base pairs and by designing the probe with an appropriate Tm. The beginning and end points of the probe should be chosen so that the length and %G and %C result in a Tm about 2-10 °C higher than the temperature at which the final assay will be performed. The importance and effect of various assay conditions will be explained further herein. Third, regions of the rRNA which are known to form strong structure inhibitory to hybridization are less preferred. Finally probes with extensive self complementarity should be avoided." (See Column 6 lines 66-67 and Column 7 lines 1-29).

With regard to Claims 11-17, Hogan et al. teaches, "while oligonucleotide probes of different lengths and base composition may be used, oligonucleotide probes preferred in this invention are between about 15 and about 50 bases in length" (see Column 10, lines 13-15). Therefore Hogan et al. teaches taking a sequence and fragmenting the sequence into smaller oligonucleotides to be used as probes. Hogan et al. teaches that these probes are preferable to be between about 15 and about 50 bases in length. Though, Hogan et al. does not specifically teach the SEQ ID Nos 1, 2, 3, 5, 6, and 7, he does suggest the fragmentation of a larger fragment (i.e. the GenBank Accession Number AE008917) into smaller oligonucleotide probes.

Therefore, the ordinary artisan would have been motivated to select any number of oligonucleotide fragments from Accession Number AE008917 including SEQ ID Nos

1, 2, 3, 5, 6, and 7 which are fragments of SEQ ID No. 4 and 8 that are contained by Accession Number AE008917. The art of designing probes (oligonucleotides) at the time the invention was made was very well described in the art. The art uses alignment programs to align sequences of interest and then uses algorithms to select and test probes and primers for their desired function of either detecting or distinguishing particular organisms. Designing probes that are equivalents to those taught in the art is routine experimentation. The prior art teaches the parameters and objectives involved in the selection of oligonucleotides that function as probes, see Hogan et al. Moreover there are many Internet web sites that provide free downloadable software to aid in the selection of probes drawn from genetic data recorded in a spreadsheet. The prior art is replete with guidance and information necessary to permit the ordinary artisan in the field of nucleic acid detection to design probes. The claimed probes are prima facie obvious over the cited references in the absence of secondary considerations, given the extensive teachings in the art. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to use the amplified sequence of Brucella as taught by Accession Number AE008917 and design constraints of probes taught by Hogan et al. to obtain equivalent alternative probes of the claimed invention. The ordinary artisan would be motivated to have designed and test new probes to obtain additional oligonucleotides that function to detect Brucella and identify oligonucleotides with improved properties.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Salmon
Examiner
Art Unit 1634

JEANINE A. GOLDBERG
PRIMARY EXAMINER
10/24/06